

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

**UNITED STATES, *et al.*,
ex rel.
MICHAEL VAUGHN, *et al.*,**

Plaintiffs

v.

UNITED BIOLOGICS, LLC, *et al.*,

Defendants

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Civil Action H-13-1081

**RELATORS' OBJECTIONS AND MOTION TO STRIKE
SUMMARY JUDGMENT EVIDENCE**

If the Court does not grant Relators' motion to dismiss this case with prejudice, Relators object to, and move to strike, the summary judgment evidence proffered by UAS, in accordance with F.R.C.P. 56(e).

A. Declarations that Violate Basic Rules of Evidence Should be Stricken

Relators object to the declarations of Thomas Thill and Kevin G. McAnaney, submitted as Exhibits A and B, respectively, to UAS's motion for summary judgment (Dkt. 89) because they are riddled with unsupported claims, speculative assertions, inadmissible hearsay, ultimate and legal conclusions, and gross mischaracterizations. As set forth below, the declarants offer opinions for which no foundation or personal knowledge is provided. Thill repeatedly asserts alleged "facts" for which he has no personal knowledge and offers objectionable conclusions about the ultimate issues presented to this Court. McAnaney offers objectionable legal conclusions as a fact

witness or improper expert testimony which is objectionable because UAS has never designated him as an expert witness in this case nor provided any report containing his opinions and legal conclusions, the declaration does not disclose the facts or documents on which such conclusions are based, and such opinions improperly go to the ultimate questions for this Court. The end result is a collection of unreliable declarations with little to no value as summary judgment evidence.

Relators' objections (though lengthy) are clear and uncomplicated. First, UAS's declarations violate the dictates of Federal Rule of Evidence 602, which permits a lay witness to testify "*only if* evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter" (emphasis added). UAS's declarations demonstrate no regard for Rule 602, as its declarants make sweeping conclusions about UAS's agreements with physicians, UAS's medical and billing practices, UAS's relationships with its physicians, and UAS's response to OIG Advisory Opinion 11-17 without any demonstrated personal knowledge.

One clear example of this lack of personal knowledge is all of the information in Thill's declaration from prior to his April 2012 employment by UAS, including UAS's prior business practices, agreements negotiated and/or executed prior to that date, UAS's alleged "understanding that the agreements were commonplace in the industry," UAS's response to the 2011 OIG Advisory Opinion 11-17, and the sample contract attached as Ex. A-1 thereto, which is dated October 28, 2011. Another example is

McAnaney's failure to demonstrate any personal knowledge regarding UAS's business model or the source of the request that prompted OIG Advisory Opinion 11-17.

McAnaney also proffers opinion or expert testimony despite not being disclosed as an expert in this case or providing any expert report setting forth his opinions and the purported facts and documents on which they are based. Such opinion testimony contravenes the requirements of Fed. R. Evid. 701, which provides that non-expert "testimony in the form of an opinion is limited to one that is: (a) rationally based on the witness's perception, (b) helpful to ... determining a fact in issue, and (c) not based on scientific, technical, or other specialized knowledge." McAnaney offer opinions about, for example, his legal conclusions and beliefs regarding OIG Advisory Opinion 11-17, including those set forth in his review, attached as Exhibit 1 to his declaration, and about his beliefs or opinions regarding the legality of UAS's business model. Such statements are also in direct violation of Fed. R. Evid. 702, which sets forth the specific requirements as to who may provide expert testimony.

Similarly, Relators object to Thill's and McAnaney's repeated assertions of broad legal conclusions, which are appropriately reserved for the Court, not interested parties and their counsel. Thill's statements that each of UAS's agreements with physicians are "voluntarily executed at arms-length, without compulsion" and his reference to the legal advice of McAnaney that UAS's "contractual arrangements were commonplace and did not violate the law" not only lack factual basis, but also constitute improper opinions on conclusions of law rather than facts and evidence to be considered in the Court's

determination of constitutionality. *See Salas v. Carpenter*, 980 F.2d 299, 305 (5th Cir. 1992) (“[c]onclusory assertions cannot be used in an affidavit on summary judgment.”); *Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1016-17 (9th Cir. 2004) (“No witness – expert or non-expert – should opine on the ultimate legal conclusion, which is province of the court.”). Similarly, McAnaney’s beliefs or opinions regarding the legality of UAS’s business model and his conclusion that UAS’s contractual arrangements with physicians, including the use of percentage based agreements, did not generate unlawful remuneration under the Anti-Kickback Statute, not only lack factual basis, but also constitute improper opinions on conclusions of law rather than facts and evidence to be considered in the Court’s determination of the issues before it.

Declarants base their declarations on mere hearsay, such as Thill’s references to McAnaney’s alleged advice, as well as all information that pre-dates his employment with UAS. Declarants offer these statements made by third parties for the truth of the matter asserted, and no hearsay exceptions apply. *See* Fed. R. Evid. 801, 802. This hearsay renders thee declarations inadmissible.

The declaration of Thomas Thill repeatedly violates Federal Rule of Evidence 1002, the best evidence rule, which provides that “[a]n original writing ... is required in order to prove its content unless these rules or a federal statute provides otherwise.” Specifically, Thill offers testimony regarding the content of the “written agreements UAS negotiates with clinics and physicians” without introducing such documents into evidence, despite the fact that such documents are within UAS’s possession and control.

And, the introduction of one sample or exemplary contract, which Thill does not (and cannot) opine is exactly like every other contract entered into by UAS and clinics or physicians, is insufficient evidence of anything beyond the four corners of this one contract with one unnamed practice group. There is no excuse for introducing the contents of all such documents through declarations rather than introducing the documents themselves.

Accordingly, UAS's declarations of Thill and McAnaney should be stricken from the summary judgement record for the foregoing reasons.

B. Evidentiary Objections to Evidence

1. Declaration of Thomas Thill, Ex. A, and Ex. A-1 thereto.

- a. **Thill Decl. ¶ 3:** "UAS began in 2009 offering support services to physicians to assist those physicians in providing allergy skin prick testing and immunotherapy to patients."

Objection 1

Lack of Personal Knowledge/Foundation [Fed. R. Evid. 602]: Thill does not provide any personal knowledge or foundation for his statements regarding UAS's business prior to his employment by UAS in April 2012.

Objection 2

Best Evidence Rule [Fed. R. Evid. 1002]: To the extent such information is based on documents, the documents provide the best evidence of such information, are within UAS's custody or control, and should have been submitted.

- b. **Thill Decl. ¶ 4:** “UAS provides a physician with all necessary support services for the provision of allergy testing and immunotherapy, including trained technicians, antigens used to create immunotherapy, supervised preparation of the immunology, protocols and supplies. UAS provides these services pursuant to written agreements UAS negotiates with clinics and physicians at arms-length. Often these negotiations involve counsel for both UAS and the physician participating in the negotiation.”

Objection 1

Lack of Personal Knowledge/Foundation [Fed. R. Evid. 602]: Thill does not provide any personal knowledge or foundation for his statement about what UAS may provide to a single physician, let alone to all physicians and clinics with whom it has contracted, or his statement that UAS provides all “necessary services for the provision of allergy testing and immunotherapy” to the physicians and clinics with whom UAS has contracted. Further, Thill provides no personal knowledge or foundation for his statements regarding the written agreements UAS negotiates with clinics or physicians, or for his assertion that such negotiations are arms-length. Finally, Thill provides no factual basis or foundation for his assertion that often such negotiations “involve counsel for both UAS and the physician.”

Objection 2

Improper Expert Testimony of Non-Expert [Fed. R. Evid. 701, 702]: Thill has not been designated as an expert in this case relating to the question of what services may be medically necessary for the “provision of allergy testing and immunotherapy”

and has presented no qualifications, knowledge or expertise that would support this conclusory opinion.

Objection 3

Improper Opinion Testimony as to a Legal Conclusion: Thill's assertion that the written agreements between UAS and physicians or clinics were negotiated at arms-length, is a legal opinion, not a fact. Thill fails to provide any facts relating to the negotiations between UAS and physicians or clinics, and whether such negotiations were at arms-length is a legal question for the Court to determine.

Objection 4

Lack of Relevance [Fed. R. Evid. 401]: What UAS may or may not provide to a single physician is not relevant to UAS's business practices with respect to all of the physicians and clinics with whom it has contracted.

- c. **Thill Decl. ¶ 5:** "As part of the agreements, the contracting clinics or physicians agree to provide the necessary professional services component of the testing and treatment, including patient examination, medical history review, medical determinations, and supervision of UAS technicians."

Objection 1

Best Evidence Rule [Fed. R. Evid. 1002]: The agreements themselves are the best evidence of what the "contracting clinics or physicians agree to provide," are within UAS's custody and control, and should have been submitted in support of the motion. Further, to the extent Thill purports to rely on the sample contract he attaches to his declaration, which Thill does not (and cannot) opine is exactly like every other contract

entered into by UAS and clinics or physicians, it is insufficient evidence of anything beyond the four corners of this one contract with one unnamed practice group.

Objection 2

Lack of Personal Knowledge/Foundation [Fed. R. Evid. 602]: Thill does not provide any personal knowledge or foundation for his statements about all of the agreements UAS may have with physicians or clinics, and what such agreements may require of the physicians or clinics.

- d. **Thill Decl. ¶ 6:** “The amount the contracting physician or clinic pays UAS for its services varies depending on the contract UAS and the physician agree to, but is set by agreement. For example, a clinic or physician may agree to pay UAS a flat fee per service UAS performs, a flat monthly fee for these services, or an amount tied to the collections the clinic or physician receives for allergy services related to UAS’s services.”

Objection 1

Best Evidence Rule [Fed. R. Evid. 1002]: The agreements themselves are the best evidence of what “the contracting physicians or clinics pays to UAS for its services,” especially given the fact that Thill admits that the amount and the basis on which the amount is calculated “varies depending on the contract UAS and the physician agree to.” Further, to the extent Thill purports to rely on the sample contract he attaches to his declaration, which Thill does not (and cannot) opine is exactly like every other contract entered into by UAS and clinics or physicians, it is insufficient evidence of anything beyond the four corners of this one contract with one redacted practice group.

Objection 2

Lack of Personal Knowledge/Foundation [Fed. R. Evid. 602]: Thill does not provide any personal knowledge or foundation for his statements about all of the agreements UAS may have with physicians or clinics, how the payment from the clinic or physician to UAS is determined, or the agreements on which he bases his examples of the various methods for determining UAS's payments for services.

Objection 3

Lack of Relevance [Fed. R. Evid. 401]: Generic examples of ways UAS's fee may be determined is not relevant to the Court's determination of whether UAS's agreements are legally compliant.

- e. **Thill Decl. ¶ 7 and Ex. A-1 thereto:** "Attached hereto as Exhibit A-1 is a true and correct copy of a contract UAS offered to clinics primarily between 2009 and 2012, in which the physician agreed to pay UAS a certain percentage of gross collections the physician received from both private insurance companies and the government for allergy services. All agreements that provide for a percentage basis of payment only vary at most by the specific percentage paid by a particular clinic or physician. UAS never executed an agreement that varies the amount of percentage paid based on the volume or amount services performed by UAS or performed or billed by the contracting clinic or physician."

Objection 1

Best Evidence Rule [Fed. R. Evid. 1002]: The agreements themselves are the best evidence of what all the agreements provide (and what they do not provide) relating to the basis of payments from the clinics or physicians to UAS. Further, to the extent Thill purports to rely on the sample contract selected by UAS that he attaches as Ex.

A-1 to his declaration, which Thill does not (and cannot) opine is exactly like every other contract entered into by UAS and clinics or physicians, it is insufficient evidence of anything beyond the four corners of this one contract with one unnamed practice group.

Objection 2

Lack of Personal Knowledge/Foundation [Fed. R. Evid. 602]: Thill does not provide any personal knowledge or foundation for his statements about the contents of all of the percentage-based agreements UAS has with physicians and clinics. Thill also does not provide any personal knowledge or foundation for the sample contract he attached to his declaration as Ex. A-1. The sample contract was entered into by UAS and the redacted physician or clinic in October 2011, prior to Thill's employment by UAS.

Objection 3

Lack of Relevance [Fed. R. Evid. 401]: Generic examples of ways UAS's fees may be determined are not relevant to the Court's determination of whether UAS's agreements are legally compliant.

- f. **Thill Decl. ¶ 8:** Each of the agreements with physicians to which UAS is a party were negotiated and voluntarily executed at arms-length, without compulsion. UAS entered into these agreements with the understanding that they were commonplace in the industry.

Objection 1

Lack of Personal Knowledge/Foundation [Fed. R. Evid. 602]: Thill does not provide any personal knowledge or foundation for his statement about the negotiation and execution of each of the agreements with physicians to which UAS is a party, or for his assertions that they were negotiated at arms-length and without compulsion, or that such agreements were commonplace in the industry.

Objection 2

Improper Expert Testimony of Non-Expert [Fed. R. Evid. 701, 702]: To the extent Thill's assertions regarding the agreements is based on the opinion provided by McAnaney, as described in Exhibit B and Ex. B-1 thereto, neither Thill nor McAnaney have been designated as an expert in this case relating to these questions, have not provided any written report setting forth their opinions or produced any documents on which those opinions are based.

Objection 3

Improper Opinion Testimony as to a Legal Conclusion: Thill's assertions that each of the agreements between UAS and physicians or clinics were negotiated at arms-length and without compulsion and that they are commonplace in the industry are legal opinions, not facts. Thill fails to provide any facts relating to the negotiations between UAS and physicians or clinics, or facts demonstrating the use of such agreements in the industry.

- g. **Thill Decl. ¶ 9:** OIG Advisory Opinion 11-17 was brought to UAS's attention in late 2011 and on numerous occasions was inaccurately attributed to UAS, which did not request the opinion. In response, UAS sought the advice of Kevin McAnaney regarding its contractual arrangements with physicians in light of OIG Advisory Opinion 11-17. UAS received Mr. McAnaney's advice as confirmation that the contractual arrangements were commonplace and did not violate the law. UAS disseminated Mr. McAnaney's opinion to physicians in contract with UAS or considering contracting with UAS with Mr. McAnaney's consent."

Objection 1

Lack of Personal Knowledge/Foundation [Fed. R. Evid. 602]: Thill does not provide any personal knowledge or foundation for his statements about the OIG Advisory Opinion 11-17, how UAS learned of it, that it was attributed to UAS, how he knows that UAS did not request the opinion, or what UAS did in response, including seeking McAnaney's opinion and disseminating it. Again, all of the actions about which he testifies occurred prior to his employment with UAS.

Objection 2

Improper Expert Testimony of Non-Expert [Fed. R. Evid. 701, 702]: To the extent Thill's assertions that UAS's "contractual arrangements were commonplace and did not violate the law" are based on the opinion provided by McAnaney, as described in Exhibit B and Ex. B-1 thereto, neither Thill nor McAnaney have been designated as an expert in this case relating to these questions, have not provided any written report setting forth their opinions or produced any documents on which those

opinions are based. Further, Thill has presented no qualifications, knowledge or expertise that would support this conclusory opinion.

Objection 3

Improper Opinion Testimony as to a Legal Conclusion: McAnaney's assertion that regarding the legality of UAS's contractual arrangements is a legal opinion on the ultimate issues to be decided by this Court, not facts. Thill fails to provide any facts or documents on which such opinions or conclusions are based.

Objection 4

Inadmissible Hearsay [Fed. R. Evid. 801(c), 802]: Thill's statements regarding the substance of McAnaney's advice regarding UAS's contractual arrangements is hearsay and is offered for the truth of the matter asserted.

- h. Thill Decl. ¶ 10:** "Hundreds of physicians in contract with UAS continue to provide services to their patients in accordance with the business arrangement reviewed by Mr. McAnaney."

Objection 1

Lack of Personal Knowledge/Foundation [Fed. R. Evid. 602]: Thill does not provide any personal knowledge or foundation for his statement about how "hundreds of physicians in contract with UAS" conduct their respective businesses, whether such businesses are conducted "in accordance with the business arrangement" McAnaney purportedly reviewed, or what that business arrangement was.

2. Declaration of Kevin G. McAnaney, Ex. B and Ex.1 thereto

- a. McAnaney Decl. ¶ 3 and Ex. 1 thereto:** “In December 2011, I reviewed the business model of United Biologics, LLC ... Specifically, I prepared an analysis as to whether UAS’s contractual arrangements would potentially violate the AKS, especially in light of the Advisory Opinion 11-17 then recently issued by the Office of the Inspector General of the United States Department of Health & Human Services (“OIG”). A true and correct copy of my review is attached as Exhibit 1 and incorporated herein by reference. UAS was advised by me that, as a legal matter, UAS’s contractual arrangements with physicians, including the use of percentage based agreements, did not generate unlawful remuneration under the AKS.”

Objection 1

Lack of Personal Knowledge/Foundation [Fed. R. Evid. 602]: McAnaney does not provide any personal knowledge or foundation for his statements about UAS’s contractual arrangements, let alone provide any facts, information or other documents on which he based his opinion as to whether such arrangements “would potentially violate the AKS” or “generate unlawful remuneration under the AKS.”

Objection 2

Improper Expert Testimony of Non-Expert [Fed. R. Evid. 701, 702]: McAnaney has not been designated as an expert in this case relating to his purported opinions regarding the legality of UAS’s contractual arrangements. McAnaney’s opinion attached to his declaration as Exhibit 1 is improper because he has not been designated as an expert witness in this case or produced any documents on which his opinions are based.

Objection 3

Improper Opinion Testimony as to a Legal Conclusion: McAnaney's conclusions regarding the legality of UAS's "contractual arrangements with physicians" is a legal opinion, not a fact. McAnaney fails to provide any facts relating to the such negotiations between UAS and physicians or clinics, or facts demonstrating the use of such agreements in the industry.

Objection 4

Inadmissible Hearsay [Fed. R. Evid. 801(c), 802]: Whatever advice McAnaney may have given UAS, including that set forth in Exhibit 1 to his declaration, is hearsay and is offered for the truth of the matter asserted.

- b. **McAnaney Decl. ¶4 and Ex. 1 thereto:** "From my review of the request for OIG Advisory Opinion 11-17, UAS did not request the opinion and by the opinion's own terms it could not be relied upon to judge the legality of UAS's business model. I advised UAS that as a matter of law, the opinion was not binding on UAS, or anyone other than the requesting party nor had the opinion concluded that the arrangement described therein was unlawful."

Objection 1

Lack of Personal Knowledge/Foundation [Fed. R. Evid. 602]: McAnaney does not provide any personal knowledge or foundation for his conclusory statements that "UAS did not request the opinion," that "it could not be relied upon to judge the legality of UAS's business model."

Objection 2

Improper Expert Testimony of Non-Expert [Fed. R. Evid. 701, 702]:

McAnaney has not been designated as an expert in this case relating to his purported opinions regarding the origin of OIG Advisory Opinion 11-17, that the Opinion was not binding on UAS, or about the legal conclusions set forth in the Opinion. Further, he has not produced any documents on which his opinions are based.

Objection 3

Improper Opinion Testimony as to a Legal Conclusion: McAnaney's conclusions regarding the legal effect of the Advisory Opinion 11-17, on whom such Opinion was binding, and what the legal conclusions of the Opinion were. Further, McAnaney fails to give any specific facts or produce any documents on which these legal conclusions are based. And, such conclusions are objectionable because they are not facts, but instead go to the very legal issues before this Court.

Objection 4

Inadmissible Hearsay [Fed. R. Evid. 801(c), 802]: Whatever advice McAnaney may have given UAS, including in his opinion attached as Exhibit 1 to his declaration, is hearsay and is offered for the truth of the matter asserted.

Objection 5

Best Evidence Rule [Fed. R. Evid. 1002]: Advisory Opinion 11-17 is the best evidence of what it contains and should have been submitted instead of McAnaney's conclusory statements regarding the content and legal effect of it.

- c. **McAnaney Decl. ¶5 and Ex. 1 thereto**: “My advice to UAS still stands today, as I believe now and I believed then, that UAS’s agreements with physicians do not violate the AKS, including its percentage based compensation arrangements. Such arrangements are common in the healthcare industry and are generally assumed not to be problematic in and of themselves.”

Objection 1

Lack of Personal Knowledge/Foundation [Fed. R. Evid. 602]: McAnaney’s beliefs regarding the legality of UAS’s compensation arrangements do not constitute competent summary judgment evidence, and he does not provide any personal knowledge or foundation for his conclusory statements. Again, McAnaney provides no facts or documentation on which such beliefs are based. Further, he offers no facts or documents to support his assertion that “such arrangements are common in the healthcare industry.” Finally, general assumptions regarding these compensation arrangements are also not competent summary judgment evidence.

Objection 2

Improper Expert Testimony of Non-Expert [Fed. R. Evid. 701, 702]: McAnaney has not been designated as an expert in this case relating to his purported opinions regarding the legality of UAS’s “percentage based compensation arrangements” or about what contracts may or may not be common and not problematic in the industry. Further, he has not produced any documents on which his opinions are based.

Objection 3

Improper Opinion Testimony as to a Legal Conclusion: McAnaney's conclusions that UAS's agreements "do not violate the AKS, including its percentage based compensation arrangements" are not facts, but rather constitute legal conclusions regarding the ultimate issues to be decided by this Court. Further, McAnaney fails to give any specific facts or produce any documents on which these legal conclusions are based.

d. Ex. 1 to McAnaney Decl.:

Objection 1

Lack of Personal Knowledge/Foundation [Fed. R. Evid. 602]: McAnaney's beliefs regarding the legality of UAS's compensation arrangements do not constitute competent summary judgment evidence because he does not provide any personal knowledge or foundation for his conclusory statements regarding UAS's business model. Exhibit 1 contains numerous paragraphs containing information about UAS's business model on which his conclusions appear to be based. McAnaney, however, fails to disclose any personal knowledge or any foundation for such factual assertions.

Objection 2

Improper Expert Testimony of Non-Expert [Fed. R. Evid. 701, 702]: McAnaney has not been designated as an expert. Further, he has not produced any documents or information on which his opinions are based. Thus, his legal conclusions

throughout Exhibit 1 regarding whether UAS's contracts comply with the AKS are inappropriate in this case.

Objection 3

Improper Opinion Testimony as to a Legal Conclusion: Exhibit 1 is replete with various McAnaney's conclusions regarding the legality of UAS's agreements. These conclusions are improper because they go to the ultimate issues to be decided by this Court. Further, while Exhibit 1 contains numerous alleged facts or factual assumptions on which his opinions are based, he produced no documents demonstrating the facts on which his legal conclusions are based.

Objection 4

Inadmissible Hearsay [Fed. R. Evid. 801(c), 802]: Whatever information McAnaney received from UAS regarding its business model or contractual arrangements, as well as any advice McAnaney may have given UAS, is hearsay and appears to be offered for the truth of the matter asserted.

Objection 5

Best Evidence Rule [Fed. R. Evid. 1002]: Advisory Opinion 11-17 is the best evidence of what it contains and should have been submitted instead of McAnaney's conclusory statements regarding the content and legal effect of it. Similarly, to the extent McAnaney's opinions are based on documents he received from UAS, those documents are the best evidence, not McAnaney's summary of the alleged facts.

3. Exhibit C-1 to Affidavit of Casey Low

Objection

Lack of Relevance [Fed. R. Evid. 401]: Jury instructions given in a 2004 criminal case in the District of Massachusetts, which may well have been proposed by agreement, are irrelevant to the determination of the legal issues before this Court for the reasons stated in Relators' response to the motion for summary judgment at pp. 11-12, in which these instructions are discussed.

PRAYER

Relators request that the Court dismiss their case with prejudice as requested in their motion to dismiss (Dkt. 90) or, in the alternative, for the reasons set forth above, sustain Relators' objections, strike UAS's summary judgment evidence, and grant Relators such further relief to which they may be entitled.

Respectfully submitted,

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**ATTORNEYS FOR RELATORS VAUGHN,
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CERTIFICATE OF SERVICE

I certify that on November 15, 2016, a true and correct copy of this document properly was served on counsel of record via electronic filing in accordance with the USDC, Southern District of Texas, Procedures for Electronic Filing.

/s/ Jan Soifer

Jan Soifer